

Appl. No. 10/034,448
Amdt. Dated Mar. 23, 2006
Reply to Office action of Jan. 6, 2006

Replacement Drawing Sheets:

The attached three sheets of drawings are submitted as formal drawings to replace the informal drawings originally filed with the application. No changes to the Figures are presented. These sheets, which include Figs. 1-17, replace the original sheets including Figs. 1-17.

Attachment: Three Replacement Sheets

REMARKS

This paper is filed in response to the Office action mailed on January 6, 2006. Claims 1-75 were previously presented in the application. By this amendment, claims 41-51, 56, 59-63, 68, and 71-75 are canceled, and claims 76 and 77 have been added, leaving claims 1-40, 52-55, 57-58, 64-67, 69-70, and 76-77 pending in the application. Of these pending claims, claims 2-16, 18, 23-38, 40, 53-55, 58, 65-67, and 70 have been at least temporarily withdrawn from consideration. Claims 1, 20, 35, 52 and 64 are amended. All pending claims stand rejected and are at issue in the present application. In view of the amendments and remarks presented herein, reconsideration and allowance of all pending claims are respectfully requested.

Amendments to the specification are presented herein to correct obvious typographical errors. Consideration and entry of these amendments are respectfully solicited.

Turning to the Office action, the drawings are objected to for being informal. Submitted herewith is a new set of replacement drawings. Consideration and entry of these new drawing sheets are respectfully requested.

In addition, the Office action objects to claim 20 for lacking antecedent basis for the phrase "the hypotube" in line 2. Claim 20 is amended herein to correct this formal matter, and therefore this ground of rejection should now be withdrawn.

Still further, the Office action rejects claims 1, 17, 20, 22, 39, 64, and 69 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,102,890 ("Stivland"). Applicants respectfully traverse this rejection.

Independent claims 1, 20, 52, and 64 as amended recite a hypotube having a tubular shaft with a main section connected to a distal section. The distal section includes a first section connected to a second section, wherein the first section is disposed between the main section and the second section. The first section includes at least one slit extending through the tubular wall and at least partially and circumferentially around the tubular wall. The second section includes a solid stinger either formed therein or attached thereto. Support for the "solid" stinger is found in the specification at page 6, lines 3-6 and lines 23-25, which describe the stinger as being an extension of the hypotube, and in Figs. 1-10 and 14-17 as originally submitted with the application, which illustrate the stinger as having a solid cross-section. It is not seen that Stivland discloses or suggests such a structure.

Instead, Stivland discloses a catheter having a necked or skived portion, which is formed by crimping the hypotube. (Col. 4, lines 7-15; Col. 5, lines 11-16). The necked portion is identified in Fig. 2 with reference numeral 146 and in Fig. 4 with reference numeral 246. In both illustrated embodiments, the hypotube distal portion is illustrated as having a wall structure enclosing a conduit, and therefore is a hollow, albeit buckled, structure through which fluid may pass. In fact, Stivland teaches the use of a polymeric sleeve 139, 239 extending around the hypotube distal end to contain fluid that might otherwise escape through cuts made in the hypotube wall. (Col. 4, lines 51-53; Col. 5, lines 8-11). Because the distal end of the hypotube is hollow, it cannot be solid as specified in the claims.

Because Stivland does not disclose each of the elements recited by the claims at issue, it follows that the claims are not anticipated thereby. In addition, Stivland fails to disclose or suggest that it would be desirable or even possible to provide a hypotube with a solid stinger, and hence a *prima facie* case of obviousness has not been established. See *In re Sernaker*, 217 U.S.P.Q. 1 (Fed. Cir. 1983) and *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. 1985).

The Office action also rejects claims 19, 21, 52, and 57 under 35 U.S.C. § 103(a) as being obvious over Stivland in view of U.S. Patent No. 6,575,958 ("Happ"). Applicants respectfully traverse this ground of rejection.

Independent claim 52, as well as claims 53-55 and 57-58 dependent directly or indirectly thereon, specifies a hypotube including, *inter alia*, a tubular shaft having a tubular wall with a distal section. The distal section includes at least one slit extending through the tubular wall and at least partially and circumferentially around the tubular wall. The distal section further includes an elongated cut-out along the tubular wall that forms a solid stinger. The at least one slit is disposed in close proximity to the stinger. Thus, the claim recites a combination of two different flexibility enhancing elements incorporated into a hypotube, namely a slit formed in the tubular wall and a solid stinger. The cited prior art fails to disclose or suggest the claimed hypotube.

As noted above, Stivland fails to disclose or suggest a hypotube having a solid stinger. In addition, Stivland fails to disclose or suggest a hypotube distal end having two different flexibility enhancing elements, namely a first portion formed with a slit and a second portion comprising a stinger. Instead, Stivland teaches the use of a single flexibility enhancing element, namely a spiral cut that extends across the entire distal section of the hypotube.

Happ fails to provide the deficiencies noted with respect to Stivland. Specifically, Happ discloses that a step may be formed in a hypotube to form a tapered tip. At no point does Happ disclose or suggest a hypotube having a combination of two different elements that alter the flexibility of the hypotube, namely a section having at least one slit and a section having a solid stinger. Accordingly, the combination of Stivland and Happ fail to disclose or suggest the claimed subject matter.

Furthermore, there is no motivation to combine Stivland and Happ in the manner suggested by the Examiner. The mere fact that references *can* be modified is *not* sufficient to establish a *prima facie* case of obviousness “unless the prior art also suggests the desirability of the combination.” *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990)” (emphasis original). In order to establish a *prima facie* case of obviousness, there must be *actual evidence* of a suggestion to modify a prior art reference or to combine two prior art references, and the suggestion to combine or modify the prior art must be clear *and particular*. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). It is improper to use hindsight to combine the prior art references, as noted in *Orthopedic Equipment Co. v. United States*, 217 U.S.P.Q. 193, 199 (Fed. Cir. 1983), which noted that “It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.” The Federal Circuit has observed that the use of hindsight can be a trap for the unwary, particularly when considering simple inventions, in noting:

Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one ‘to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.’ Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.

In re Dembiczak, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 2000)(citations omitted)(emphasis added)

It is important to consider the invention as a whole when determining obviousness; it is improper to simply focus on the differences between the claimed subject matter and the prior art. *Hybritech Inc. v. Monoclonal Antibodies*, 802 F.2d 1267, 231 U.S.P.Q. 91 (Fed. Cir. 1986). That a claimed invention incorporates old elements does not, in itself, determine obviousness. *Custom Accessories, Inc. v. Jeffrey-Allan Industries*, 807 F.2d 955, 1 U.S.P.Q.2d 1196, 1198 (Fed. Cir. 1986). Claimed inventions consisting of old elements are subject to the same standards for determining patentability. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 U.S.P.Q. 871 (Fed. Cir. 1983). The proper inquiry when determining nonobviousness is whether “there is something in the prior art as a whole *to suggest* the desirability, and thus the obviousness, of making the combination.” *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556, 225 U.S.P.Q. 26, 31 (Fed. Cir. 1985) (emphasis in original). With the foregoing as guidance, it is clear that the proposed combination of Stivland and Happ is improper.

First, the Examiner incorrectly states that Happ teaches the use of a cut-out to improve flexibility.¹ At no point does Happ assert that its tapered tip improves flexibility. Instead, Happ teaches that flexibility characteristics in the transition between a relatively rigid proximal shaft and a relatively flexible distal shaft are improved by providing a tubular support member 130. The tubular support member 130 is attached between the proximal and distal shafts and around the distal end of the hypotube. It includes a composite tubular member 148, which preferably includes a tubular metallic member 151, which may be a layer of metallic strand 154, sandwiched between inner and outer layers 160, 163 of high strength polymeric materials. (Col. 5, line 49 to Col. 6, line 4). Accordingly, Happ teaches the use of a composite, multi-layered tubular member to improve flexibility, rather than a hypotube incorporating two different flexibility enhancing elements. This interpretation of Happ finds support in the claims, which specifically recite a “tubular support member” but at no point mention a hypotube. Consequently, the Office action incorrectly asserts that Happ teaches an elongated cut-out in the hypotube distal end for providing greater flexibility, and therefore no valid motivation to combine the references has been identified.

¹ On Page 4 of the Office action, the Examiner states, “Happ et al teaches that it is known to have a hypotube (94) with an elongated cut-out in the axial direction along the tubular wall (Fig. 1, 118) for the purpose of providing the transition (118) with greater flexibility than the proximal section to improve resistance to kinking while increasing flexibility.”

Not only does the Office action fail to identify a valid motivation to combine, but no such motivation actually exists. The claimed apparatus addresses the problem of excessive strain in the connection between a hypotube and a distal shaft by forming the hypotube with two different flexibility-enhancing elements. Stivland addresses a similar problem by incorporating a single element into the hypotube in the form of a spiral cut across the entire distal portion. Happ specifically teaches that this problem may be addressed by providing a tubular support member that is separate from the hypotube. Accordingly, one of ordinary skill in the art looking to relieve stress would not be motivated to modify the hypotube of Stivland with the disclosure in Happ since Happ specifically teaches that this problem is addressed by providing an element separate from the hypotube.

In addition, the proposed combination would render the Stivland device unsatisfactory for its intended purpose. Stivland teaches that a spiral cut is to be made across the entire distal end of the hypotube, resulting in a continuous, spiral shaped hypotube distal end. Happ discloses a tapered hypotube tip formed by removing a portion of the hypotube. If the spiral distal end of Stivland is tapered by removing a portion of the hypotube, as disclosed in Happ, the distal tip will be divided into multiple, unconnected tip pieces, rendering assembly overly difficult if not impossible. Furthermore, the multiple tip pieces would exacerbate the problem of kinking in this area of the catheter. Accordingly, the proposed combination of references is improper and the rejection based thereon must be withdrawn.

Claim 57 depends from claim 52, and therefore is patentable over the cited prior art for the same reasons presented above. Furthermore, independent claims 1, 20, and 64, as well as the claims depending therefrom, recite the same elements noted above with respect 52, and therefore these claims are also patentable over the combination of Stivland and Happ.

Applicant further requests rejoinder of the claims previously withdrawn in response to the election of species requirement. The Office previously asserted both a restriction requirement between the apparatus and method claims originally presented and an election of species requirement. In this response, all of the withdrawn method claims have been canceled. Certain of the remaining apparatus claims were withdrawn in view of the election of species requirement. Each of these claims, however, depends from one of independent claims 1, 20, 52, and 64, which Applicant submits are now in condition for allowance. Accordingly, each of the remaining withdrawn claims recites each of the elements of an allowable claim, and therefore is eligible for rejoinder. Applicant notes that the amendment

to withdrawn claim 35 corrects an error in identifying the claim from which it depends. Furthermore, new claims 76 and 77 are drawn to a non-elected species, but depend from claim 64, which is now in condition for allowance, and therefore may be properly joined in this application. Reconsideration and withdrawal of the election of species requirement are therefore respectfully requested.

CONCLUSION

It is submitted that the present application is in good and proper form for allowance. A favorable action on the part of the Examiner is respectfully solicited.

If, in the opinion of the Examiner a telephone conference would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

The Commissioner is authorized to charge any fee deficiency required by this paper, or credit any overpayment, to Deposit Account No. 50-3629.

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Respectfully submitted,

By 

Brent E. Matthias

Registration No.: 41,974

MILLER, MATTHIAS & HULL

One North Franklin Street

Suite 2350

Chicago, Illinois 60606

(312) 977-9902

Attorney for Applicant